

REMARKS

Reconsideration of the Final Office Action mailed February 17, 2004, (hereinafter "instant Office Action") and withdrawal of the rejection of claims 1-3 are respectfully requested. Applicants have enclosed a Notice of Appeal with this Reply.

In the instant Office Action, claims 1-3 are listed as pending and claims 1-3 are listed as rejected.

Applicants gratefully note that the rejection of claim 7 under 35 U.S.C. §112, second paragraph, the rejection of claims 1-3 and 7 under 35 U.S.C. §103(a), the rejection of claim 8 under 35 U.S.C. §102(e) and the rejection of claim 8 under 35 U.S.C. §101 as claiming the same invention as that of claims 5 and 6 of U.S. Patent No. 6,403,641, are withdrawn.

The Examiner has rejected Claims 1-3 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,403,641 (Heal et al.), alleging that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to the treatment of co-morbid conditions associated with obesity, while the patented claims are directed to the treatment of obesity, *per se*, in which the same combination of active agents are employed". Applicants respectfully traverse this rejection. The general rule in considering the judicially created doctrine of obvious-type double patenting rejection is that:

[i]n considering the question of obvious variation, the patent disclosure may not be used as prior art. . . . This is not meant to infer that the disclosure may not be used at all. It may, for instance, be used as a dictionary to learn the meaning of the terms of the claim. It would not be appropriate, however, to indiscriminately use all the generalities of the disclosure. It is only that which is related to and supportive of the claim of the invention that may be used to determine the scope of the claim.

Phillips Petroleum Co. v. U.S. Steel Corp., 673 F. Supp. 1278, 6 USPQ2d 1065, 1090 (D. Del. 1987), *aff'd*, 865 F.2d 1247, 9 USPQ2d 1461 (Fed. Cir. 1989). Thus, only the claims of the instant application can be compared with the claims of U.S. Patent No. 6,403,641. Applicants submit that claims 1-3 of the instant application are not obvious in view of claims 1-3 of application U.S. Patent No. 6,403,641. Claims 1-3 of U.S. Patent No. 6,403,641 are directed to treatment of obesity, whereas the instant application is directed to treatment of co-morbid conditions associated with obesity. Co-morbid conditions are separate and distinct from obesity.

A co-morbid condition increases the risk of disability and premature death. Examples of co-morbid conditions, which Applicants list on page 3, lines 6-13, include non-insulin dependent diabetes mellitus, impaired glucose tolerance, hypertension, stroke, cerebral ischaemia and panic attacks. Each of these is recognized as a distinct disorder.

In order for an invention to be considered obvious under 35 U.S.C. 103(a), the invention must be considered as a whole, there must be some motivation or suggestion in the prior art reference itself to modify the reference, and there must be a reasonable expectation of success.

The Court of Appeals for the Federal Circuit has stated the following on the issue of obviousness:

Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F. 2d 1044, 1051-52, 5 USPQ 1434, 1438 (Fed. Cir. 1988), cert. denied, 109 S. Ct. 75 (1988), on remand, 13 USPQ2d 1192 (D. Conn. 1989) "Something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination."; *In re Stencel*, 828 F. 2d 751,755, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987) obviousness cannot be established "by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion that the combination be made." *Alco Standard Corp. v. Tennessee Valley Authority*, 808 F. 2d 1490, 1498, 1 USPQ2d 1337, 1343 (Fed. Cir. 1986), cert. dismissed, 108 S. Ct. 26 (1987) "the question is not simply whether the prior art 'teaches' the particular element of the invention, but whether it would 'suggest the desirability, and thus the obviousness, of making the combination.'"; *Carella v. Starlight Archery*, 804 F. 2d 135,231 USPQ 644 (Fed. Cir. 1986); *ACS Hospital Sys., Inc. v. Montefiore Hospital*, 732 F. 2d 1572, 221 USPQ 929 (Fed. Cir. 1984) "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so."

Donald S. Chisum, Patents, A Treatise on the Law of Patentability, Validity and Infringement, Vol. 2, 5-218, 1992.

The Examiner has not established a *prima facie* case of obviousness. In order to have a *prima facie* case of obviousness, there must be a specific suggestion or motivation to modify the reference, there must be an expectation of success and the prior art reference must teach or suggest all of the claim limitations.

The Examiner has not pointed to any suggestion or motivation for one skilled in the art to modify U.S. Patent No. 6,403,641, nor has the Examiner presented any line of argument as to why one skilled in the art would be motivated to use the combination of sibutramine and orlistat

to treat co-morbid conditions. As stated in *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985):

To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. (emphasis added)

Without such an express suggestion or an explanation as to why the Examiner alleges the claims to be obvious, the standard for a *prima facie* case of obviousness is not met. Claims 1-3 of U.S. Patent No. 6,403,641 do not disclose, teach or suggest the use the combination of sibutramine and orlistat to treat co-morbid conditions associated with obesity. There is no motivation in Claims 1-3 of U.S. Patent No. 6,403,641 to use the combination of sibutramine and orlistat to treat co-morbid conditions associated with obesity.

Therefore, the rejection of Claims 1-3 under the judicially created doctrine of obviousness-type double patenting over claims 1-3 of U.S. Patent No. 6,403,641 is obviated and should be withdrawn.

No fees are due for the instant amendment since the total number of claims after entry of the amendments hereinabove is not more than the total number of claims that Applicants have paid for to date.

Based upon the foregoing, Applicants believe that claims 1-3 are in condition for allowance. Prompt and favorable action is earnestly solicited.

If the Examiner believes that a telephone conference would advance the condition of the instant application for allowance, Applicants invite the Examiner to call Applicants' agent at the number noted below.

Respectfully submitted,

Date: June 17, 2004

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